

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison Between Topical Niosomal Zinc Sulfate Combined With Cryotherapy Versus topical simple Zinc sulfate Combined With Cryotherapy In The Treatment Of Verruca Vulgaris

Protocol summary

Study aim

Comparison Between Topical Niosomal Zinc Sulfate Combined With Cryotherapy Versus topical simple Zinc sulfate Combined With Cryotherapy In The Treatment of Verruca Vulgaris

Design

This study is a double-blind ,randomized clinical trial with control group and parallel group design

Settings and conduct

This is a double-blind randomized clinical trial study. 60 patients with common warts greater than 6 mm from both sexes over 12 years of old,attending Afzalipour Hospital in Kerman enrolled the study. Patients were allocated to 2 groups (intervention and control). Intervention group will receive cryotherapy with niosomal zinc sulfate solution and the control group will receive cryotherapy with simple zinc sulfate solution.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients older than 12 years old. Exclusion criteria: patients younger than 12 years old; immunocompromised patients, and those who have previously received treatment for warts. Pregnant or lactating women have facial, genital, and nail warts.

Intervention groups

Patients in case group were received cryotherapy with niosomal zinc sulphate solution (twice daily) and in control group received cryotherapy with simple zinc sulfate solution (twice daily).

Main outcome variables

Measurement of lesions: severity of warts

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190809044483N1**

Registration date: **2019-09-11, 1398/06/20**

Registration timing: **prospective**

Last update: **2019-09-11, 1398/06/20**

Update count: **0**

Registration date

2019-09-11, 1398/06/20

Registrant information

Name

Roozbeh Mehrabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3261 5720

Email address

r.mehrabadi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-02, 1398/07/10

Expected recruitment end date

2019-12-31, 1398/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Between Topical Niosomal Zinc Sulfate Combined With Cryotherapy Versus topical simple Zinc sulfate Combined With Cryotherapy In The Treatment Of Verruca Vulgaris

Public title

The effect of zinc sulfate in the treatment of common warts

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with common warts

Exclusion criteria:

Patients under 12 years Patients with immunodeficiency

Patients who have already received treatment for warts

Pregnancy Breastfeeding Facial warts Genital warts

Warts around the nail

Age

From **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was done using Minitab 16 software (Minitab Inc.)

Blinding (investigator's opinion)

Triple blinded

Blinding description

This is a triple-blind study for outcome assessor, patients and analyzer. Both drugs were kept in identical amber glass containers, so the evaluating physician and patients were unaware of the containers.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kerman University of Medical Sciences

Street address

Ebne Sina Ave., Tahmasb Abad Blvd.

City

kerman

Province

Kerman

Postal code

761614111

Approval date

2019-01-30, 1397/11/10

Ethics committee reference number

IR.KMU.AH.REC.1397.135

Health conditions studied**1****Description of health condition studied**

Common wart

ICD-10 code

B07

ICD-10 code description

Viral warts

Primary outcomes**1****Description**

Measurement of wart lesion size

Timepoint

At base line and 2,4,6,8,12 weeks later

Method of measurement

Measurement of lesion size by physical examination

Secondary outcomes**1****Description**

Hyperpigmentation

Timepoint

At baseline (before intervention) and weeks 2,4,6,8,12

Method of measurement

By physical examination

2**Description**

Hypopigmentation

Timepoint

At baseline (before intervention) and weeks 2, 4, 6, 8, 12

Method of measurement

By physical examination

3**Description**

Atrophic scar

Timepoint

At baseline (before intervention) and weeks 2, 4, 6, 8, 12

Method of measurement

By physical examination

Intervention groups

1

Description

Intervention group: niosomal Zinc sulfate solution, Route of administration : Topical application, twice daily, Duration of treatment: 12 weeks, Manufactured factory: Sorbital esters (Span compounds) and polyoxyethylene derivatives of sorbital esters (Tween compounds),The concentration of zinc sulfate used in the formulation was 2%. Chemicals and soluble materials were prepared by Merck Elemental and Sigma America and carl-roth Elemental, and is imported by Shafa.

Category

Treatment - Drugs

2

Description

Control group: Simple Zinc Sulfate Solution, Route of administration : Topical application, twice daily, Duration of treatment: 12 weeks, Preparation of topical simple zinc sulfate: Zinc sulfate dissolving in hot distilled water (90 ° C) 4% at base of eucerin.As such, after diluting at the base of eucerin, the final concentration of sulfate will be 2% by volumetric weight.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

Mahin Aflatoonian

Street address

Imam high way,Kerman

City

Kerman

Province

Kerman

Postal code

7616913911

Phone

+98 34 3132 8328

Email

maafatoonian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

Ebne sina Avenue,Jehad Blvd

City

Kerman

Province

Kerman

Postal code

7619813159

Phone

+98 34 3855 3226

Email

abpardakhty@kmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mahin Aflatoonian

Position

Assistant professor of dermatology

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

Street address

Afzalipour Hospital ,Imam Highway

City

Kerman

Province

Kerman

Postal code

7616913911

Phone

+98 34 3132 8328

Email

maafatoonian@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

مهين افلاطونيان

Position

Assistant professor of dermatology

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

Street address

Afzalipour Hospital, Imam Highway

City

Kerman

Province

Kerman

Postal code

7616913911

Phone

+98 34 3132 8323

Email

maafatoonian@gmail.com

+98 34 3132 8328

Email

maafatoonian@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All of the data can be shared after unidentifiable people.

When the data will become available and for how long

Start the access period 6 months after publishing the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any analysis of the data is allowed but not published. A written request with a valid letter from a university or scientific institution with an identification card is required.

From where data/document is obtainable

Roosbeh Mehrabadi

What processes are involved for a request to access data/document

A written request will be submitted to the research Vice-chancellor of the Kerman University of Medical Sciences with a valid letter from the University or institute.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Mahin Aflatoonian

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

Street address

Afzalipour Hospital, Imam Highway

City

Kerman

Province

Kerman

Postal code

7616913911

Phone